DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

P940007

Memorandum

Date JUL 20 1995

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Pharmacia, Inc.
Model WS-100 Pliolens Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens - ACTION

To The Director, CDRH
ORA ____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Philip J. Phillips
for Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved ___ Disapproved ___ Date _____

Prepared by Ashley A. Boulware, CDRH, HFZ-460, July 13, 1995, 594-2053

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. _____]

PHARMACIA; PREMARKET APPROVAL OF MODEL WS-100 PLIOLENS ULTRAVIOLET-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Pharmacia, Inc., Dublin, OH, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of Model WS-100 Pliolens ultraviolet-absorbing silicone posterior chamber intraocular lens.

DATE: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Drive, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Ashley A. Boulware

Center for Devices and Radiological Health (HFZ-460)

Food and Drug Administration

9200 Corporate Blvd.

Rockville, MD 20850

301-594-2053.

SUPPLEMENTARY INFORMATION: On February 28, 1994, Pharmacia, Inc., Dublin, OH 43017, submitted to CDRH an application for premarket approval of Model WS-100 Pliolens ultraviolet-absorbing silicone posterior chamber intraocular lens. The device is a posterior chamber intraocular lens and is indicated for primary implantation for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by extracapsular cataract extraction.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On JUL 20 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon

written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

OPPORTUNITY FOR ADMINISTRATIVE REVIEW

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FR), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. This notice is issued under the Federal Food, Drug, and Cosmetic Act section 520(h), 90 Stat. 554-555, 571 (21 U.S.C. 360e(d),

360j(h)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated:_____.

_____

D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jean Frydman
Director, Regulatory Affairs
Pharmacia, Inc.
7001 Post Road
Dublin, OH 43017

JUL 20 1995

Re: P940007
Model WS-100 Pliolens Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens (IOL)
Filed: February 28, 1994
Amended: May 9, September 9, September 21, December 2 and December 20, 1994; February 10, March 23, April 21, June 6, June 30, July 7, and July 11, 1995

Dear Ms. Frydman:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for Model WS-100 Pliolens ultraviolet-absorbing silicone posterior chamber intraocular lens. This device is indicated for primary implantation for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by extracapsular cataract extraction. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

CDRH approval is subject to full compliance with the conditions described in the enclosure and the following:

1. Registration of all patients receiving the above-referenced intraocular lens must be continued and the data base shall be maintained indefinitely, or until the applicant is otherwise notified.

2. A way of facilitating adverse reaction reporting, such as an 800 telephone number, must be maintained.

3. FDA notes your agreement that you will continue postoperative follow-up for three years on 500 subjects derived from the core subjects (and modified core, if necessary) to assess further the long-term safety and effectiveness of your silicone IOL. At the completion of the postapproval study, you must submit the clinical data and update your labeling accordingly.

4. Advertising and other printed materials prepared by your firm or its distributors will not include indications or claims not included in the FDA-approved labeling for the device, e.g., that the use of this lens (or that small incision surgery) results in more rapid visual recovery, decreased surgically-induced astigmatism, improved overall quality of vision, or similar claims.

Expiration dating for this device has been established and approved at 5 years.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that as soon as possible, and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Ms. Ashley A. Boulware at (301) 594-2053.

Sincerely yours,

for Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

A. Premarket Approval Application (PMA) Number: P940007
Date Filed: February 28, 1994
Date Approved: JUL 20 1995

B. Generic Name of Device: Posterior Chamber Intraocular Lens (IOL)

C. Trade Names of Device: Pliolens Model WS-100 Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens

D. Applicant's Name and Address:
Pharmacia, Inc.
7001 Post Road
Dublin, OH 43017

E. Good Manufacturing Practice (GMP) Inspection Dates:
Date of Inspection (Irvine, CA Facility): January 27, 1995
Conclusion: The manufacturing site was found to be in compliance with device GMP requirements.

F. Ophthalmic Devices Panel (Panel): N/A

II. INDICATIONS

Pharmacia, Inc.'s Pliolens Model WS-100 Silicone Posterior Chamber Intraocular Lens (IOL) is indicated for primary implantation for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by extracapsular cataract extraction. This lens is intended for placement in the capsular bag. Since the clinical study of Model WS-100 was conducted with the lens being intended for implantation in the capsular bag, there is insufficient clinical data to demonstrate its safety and efficacy for placement in the ciliary sulcus.

III. SUMMARY

The applicant has performed nonclinical and clinical testing on this device in accordance with the FDA guidance document for testing intraocular lenses dated June 9, 1980. Nonclinical testing demonstrates the safety and effectiveness of this device from microbiology, toxicology, engineering, and manufacturing

perspectives. Data on 513 patients followed postoperatively for 12-14 months were clinically and statistically evaluated against historical controls. The population at risk for developing visually-disabling cataracts and needing cataract surgery is typically elderly; the elderly population has a slightly higher proportion of females to males. The average age of the cohort subjects was 73.3 years at the time of surgery; 62.3% of the cohort subjects were female and 37.7% were male. The inclusion/exclusion criteria did not exclude patients on the basis of gender or gender-related pathology. The study population was 88.4% Caucasian, 7.7% African-American, and 3.9% other. In this study, which began in 1990, all patients who met the inclusion criteria were included in the study.

In 1983 Stark et al. (Ophthalmology, 90(4): 311-317) published a grid of historical clinical data established from review of 45,543 eyes implanted with IOLs PMA-approved before 1982. FDA adopted the grid, which includes adverse reaction rates, sight-threatening complication rates and visual acuity results, for comparison to new lens models. Based on the analysis of the detailed data presented in the PMA, it was determined that the clinical performance of Model WS-100 compares favorably with the grid of historical data (refer to Section IV.B. Safety and Effectiveness Data). In the case of cumulative endophthalmitis, hypopyon and intraocular infection, the incidences of these complications and adverse reactions exceeded the grid values but were not statistically significant; in addition, close analysis did not reveal a lens-related etiology. While patients who experience these complications are less likely to achieve a final visual acuity of 20/40 or better, the detailed data presented in the PMA demonstrate that the benefits outweigh the risks when the device is implanted in accordance with the indications described above in Section II and in the approved labeling. The only statistically significant difference between male and female eyes was with respect to preoperative pathologies; males with pathologies were less likely than females to achieve visual acuities of 20/40 or better. Postoperative sight-threatening complication and adverse reaction rates were not significantly different when compared by gender. The overall and best-case visual acuity rates are within FDA grid values for both genders.

IV. SAFETY AND EFFECTIVENESS DATA

A. Nonclinical Studies

The applicant conducted a battery of in vivo and in vitro acute and chronic toxicity tests that establish the biocompatibility of the lens materials. These studies, combined with data from chemistry and engineering analyses, demonstrate the suitability of the material and overall device design for use in an intraocular lens. The adequacy of the manufacturing processes,

including sterilization, was established through review of the manufacturing information in the PMA as well as through on-site inspections.

B. Clinical Studies

Overall Visual Acuity (20/40 or better), Cohort = 513		FDA Grid
Age < 60 Years	100.0% [29/29]	93.7%
Age 60-69 Years	96.5% [136/141]	90.8%
Age 70-79 Years	95.5% [213/223]	88.6%
Age > 80 Years	87.5% [105/120]	75.2%
All Ages Combined	94.2% [483/513]	88.0%
Best Case, All Ages Combined	95.8% [410/428]	94.0%

Adverse Reactions (Core = 622)		
Hypopyon	0.7% [4]	0.4%
Intraocular Infection	0.3% [2]	0.1%
Acute Corneal Decompensation	0.0% [0]	0.2%
Surgical Reintervention	0.0% [0]	2.0%

Postoperative Complications (Cohort = 513)		
Cumulative Hyphema	1.0% [5]	1.0%
Cumulative Macular Edema	1.1% [6]	3.5%
Persistent Macular Edema	0.0% [0]	0.8%
Cumulative Pupillary Block	0.2% [1]	0.3%
Persistent Secondary Glaucoma	0.2% [1]	0.5%
Persistent Cyclitic Membrane	0.0% [0]	<0.1%
Persistent Vitritis	0.0% [0]	0.1%
Cumulative Retinal Detachment	0.0% [0]	0.5%
Cumulative Endophthalmitis	0.4% [2]	<0.1%
Persistent Corneal Edema	0.6% [3]	0.6%
Persistent Iritis	0.4% [2]	1.0%
Cumulative Lens Dislocation	0.0% [0]	0.4%

* Best Case: Excludes patients with preoperative ocular pathology or macular degeneration at any time.

V. CONCLUSION

The Center for Devices and Radiological Health (CDRH) reviewed the PMA and concluded that the PMA contained sufficient valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the device under the prescribed indications for use. In accordance with the provisions of section 515(c)(2) of the Federal Food, Drug and Cosmetic Act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel for review and recommendation because the information in the PMA substantially duplicates the information previously reviewed by this panel. CDRH approved this PMA in a letter to the PMA applicant dated JUL 20 1995 and signed by the Director, Office of Device Evaluation.

DRAFT LABELING

The following represents the draft edition of the product labeling to be used with the Model WS-100 silicone posterior chamber intraocular lens with UV absorber.

PHARMACIA
~~Iovision~~, Inc. Model WS-100
UV ABSORBING
SILICONE POSTERIOR CHAMBER LENS

For the replacement of the human lens in the visual correction of aphakia.

CAUTION

Federal law restricts this device to sale by, or on the order of, a physician.

DESCRIPTION

PHARMACIA
~~Iovision~~, Inc., Silicone Posterior Chamber Intraocular Lenses are biconvex optical lenses designed to be implanted in the capsular bag following extracapsular cataract extraction or phacoemulsification.

INDICATIONS

Silicone posterior chamber intraocular lenses are indicated for primary implantation for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by phacoemulsification or extracapsular cataract extraction. These devices are intended to be placed in the capsular bag.

NOTE:

Since the clinical study of Model WS-100 was conducted with the lens being implanted in the capsular bag only, there is insufficient clinical data to demonstrate its safety and efficacy for placement in the ciliary sulcus.

WARNINGS

The safety and effectiveness of this lens if placed in the anterior chamber has not been established.

These lenses are not intended for the correction of refractive error for patients who do not have a cataract.

When considering the implantation of IOLSs of powers at the extreme ends of the available power range, special consideration should be given to the dimensions of these lenses in relation to the anatomical clearances of the patient's eyes. The potential impact of factors such as optic central thickness, optic edge thickness, overall lens size on these patients' long-term clinical outcome must be carefully weighed against the potential benefit associated with the implantation of an IOL, and the patients' clinical progress should be carefully monitored.

Do not resterilize this intraocular lens by any method.

Do not store lenses at temperatures over 45 Centigrade (113 F).

Use only sterile intraocular irrigating solutions (eg.; balanced salt or normal saline solution) to rinse and/or soak lenses.

PRECAUTIONS

A high level of surgical skill is required for intraocular lens implantation. A surgeon should have observed and/or assisted on numerous surgical implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.

Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:

1. Recurrent severe anterior or posterior segment inflammation or uveitis.

2. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.

3. Surgical difficulties at the time of cataract extraction which might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).

4. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.

5. Circumstances that would result in damage to the endothelium during implantation.

6. Suspected microbial infection.

7. Safety and effectiveness in children under the age of 18 has not been established. Children under the age of 2 years are not suitable candidates for intraocular lenses.

8. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.

ADVERSE EVENTS

The complications experienced during the clinical trial of Model WS-100 include (in order of frequency): iritis, corneal edema, secondary glaucoma, macular edema, hyphema, vitritis, endophthalmitis, cyclitic membrane and pupillary block.

Additional complications may include but are not limited to the following: corneal endothelial damage, non-pigment precipitates, vitreous loss, pupillary block, iris prolapse, vitreous wick syndrome and/or uveitis.

LENS CHARACTERISTICS

The optical portion has the capability of being folded prior to insertion allowing the lens to be inserted through an incision as small as 3.0 mm while preserving a full size lens body after implantation. The physical properties of the lenses are:

LENS OPTIC

* Material: MED 6820 (Medical Grade Silicone Elastomer)

* Light transmittance:

  UV cutoff at 10% T for a 5 diopter lens = 363 nm.

  UV cutoff at 10% T for a 30 diopter lens = 368 nm.

* Diameter: 6.0 mm.

* Specific gravity: 1.05

* Index of refraction: 1.43

* Dioptric power: 5.0-28.5 diopters in 0.5 diopter increments

LEGEND:

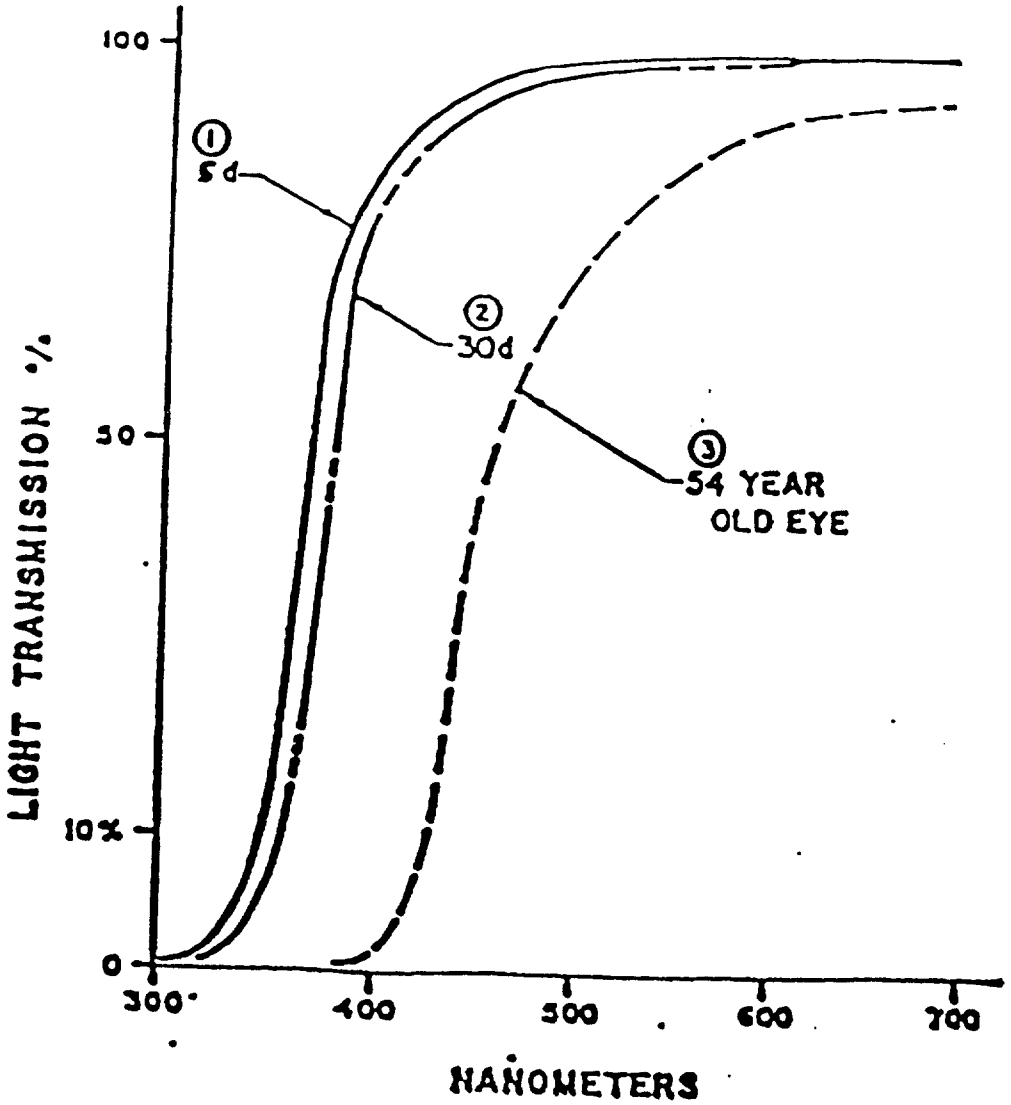
Curve 1: Spectral Transmittance (T) Curve corresponding to the central region of a 5 diopter (IOL), UV cut-off at 10% T is 363 nm.

Curve 2: Spectral Transmittance (T) Curve corresponding to the central region of a 30 diopter (IOL), UV cut-off at 10% T is 368 nm.

Curve 3: Spectral Transmittance (T) Curve* corresponding to a 53 year old phakic eye.

Note: The cut-off wavelengths and the spectral transmittance curves represent the range of transmittance values of IOLs made with this material.

* Boettner, E.A. and Wolter, J.R. 1962. Transmission of the ocular media. Investigational Ophthalmology. 1:776-783.



HAPTICS

* Configuration: Modified-J
* Material: USP Grade Blue Polypropylene Monofilament
* Diagonal Length: 14.0 mm

MODE OF ACTION

When implanted, silicone posterior chamber lenses replace the natural lens of the eye and function as a refracting medium in the correction of aphakia. The effectiveness of UV absorbing lenses in reducing the incidence of retinal disorders has not been established.

CALCULATION OF LENS POWER

The physician should determine preoperatively the power of the lens to be implanted. Lens power calculation methods are described in the following references:

1. Binkhorst, R.D., Intraocular Lens Power Calculation Manual, New York, Richard D. Binkhorst; 1978.
2. Retzlaff, J., Sanders, D., and Kraff, M.: A Manual of Implant Power Calculation, 1981.

The effective lens position is defined as the distance between the apex of the cornea to the first principal plane of the intraocular lens. For Model WS-100 this distance was calculated to be 5.2 mm. Effective lens position is described in the following references:

1. Holladay, K.J., Praeger, T.C., Chandler, T.Y., et al. A three-part system for refining intraocular lens power calculations, J. Cataract & Refractive Surgery, January 1988; 14:17-24.
2. Retzlaff, J.A., Sanders, D.R., and Fraff, M.C. Development of the SRK/T intraocular lens implant power calculation formula. J. Cataract & Refractive Surgery, May 1990; 16:333-340.

DIRECTIONS FOR USE

1. Examine the label on the lens package for proper lens model, diopter power and expiration date.

2. Open the package and check the diopter power of the lens contained within.

3. Transfer the lens, using sterile technique, into a container of sterile intraocular irrigating solution.

4. Various surgical procedures are available. The surgeon should select a procedure which is appropriate for the patient.

5. Handle the lens by the haptic and do not manipulate the optic with forceps.

6. Iovision, Inc. recommends using only the following lens folding instruments to insert its silicone posterior chamber intraocular lenses:

* Fine Folder
* Faulkner Folder
* Livernois Folder
* McDonald Folder
* PhacoFolder II
* McDonald II Folder

NOTE: The lens may experience an electrostatic charge upon opening the package. The lens should be carefully examined to ensure that particles have not been attracted to it.

HOW SUPPLIED

The contents of the inner and outer peel pouches are sterile unless they are damaged or otherwise visually compromised. These lenses are sterilized by ethylene oxide and are supplied in a lens case within a double aseptic transfer peel pouch.

EXPIRATION DATE

Sterility is guaranteed unless the sterility pouch is damaged or otherwise compromised. There is a sterility expiration date that is clearly indicated on the outside of the lens box. The lens should not be used after the expiration date indicated.

RETURN LENS POLICY

The lens may be returned for credit within 30 days of purchase. After 30 days, it can be replaced or exchanged at no charge.

PATIENT INFORMATION

It is recommended that each patient receive information regarding intraocular lenses in a manner that is suitable to the patient. This information should be provided prior to the decision to implant an intraocular lens. Postoperative information should be also provided by the physician.

PATIENT REGISTRATION INSTRUCTIONS AND REPORTING

Registration

Each patient who receives a ~~Iovision~~ PHARMACIA, Inc. Silicone Posterior Chamber Lens must be registered with ~~Iovision~~ PHARMACIA, Inc. at the time of the lens implantation.

Registration may be achieved by completing and returning the Implant Registration Card enclosed within the lens box to Iovision, Inc. This registration is important for the Iovision, Inc. patient follow-up program and will help in responding to Adverse Reaction Reports and/or potentially sight-threatening complications.

An Implant Identification Card is supplied in the lens packaging. This card should be given to the patient with instructions to keep it as a permanent record of the implant and to show the card to any eye care practitioner seen in the future.

Reporting

Adverse reactions and/or potentially sight-threatening complications that may be reasonably regarded as lens related and that were not previously expected in nature, severity or incidence must be reported to Iovision, Inc. This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation, especially in younger patients.

Purpose: Physicians must report these events in order to aid in identifying emerging or potential problems with silicone posterior chamber intraocular lenses. These problems may be related to a specific lot of lenses or may be indicative of long-term problems associated with these lenses or with IOL's in general.

CLINICAL TRIAL

Clinical trials of Model WS-100 were initiated on July 12, 1990. The results in 513 cohort patients followed for one year provide the basis for the data which were used to determine that this IOL design is reasonably safe and effective for the visual correction of aphakia.

Patient Population

The core population in the clinical trials consisted of 622 patients 63.2% females and 36.8% males; 87.0% were Caucasian, 9.1% were Black, 3.9% were reported as "Other". The mean age for the total population was 73.0 years.

TABLE 1

VISUAL ACUITY

BEST CASE COHORT

The following is a summary of final visual acuity (one year postoperatively) achieved by Cohort subjects who do not have a preoperative ocular pathology or postoperative macular degeneration (Best Case Cohort)

Age Group	Total Count	20/40 or better		20/41 - 20/80		20/81 - 20/100		20/101- 20/200		20/201+	
		Count	%	Count	%	Count	%	Count	%	Count	%
< = 59	29	29	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
60 - 69	127	124	97.6%	3	2.4%	0	0.0%	0	0.0%	0	0.0%
70 - 79	181	176	97.2%	3	1.7%	0	0.0%	2	1.1%	0	0.0%
> = 80	91	81	89.0%	9	9.9%	1	1.1%	0	0.0%	0	0.0%
	428	**410**	**95.8%**	**15**	**3.5%**	**1**	**0.2%**	**2**	**0.5%**	**0**	**0.0%**

TABLE 2

VISUAL ACUITY OUTCOME OF ALL COHORT PATIENTS

The following is a summary of final visual acuity (one year postoperative) achieved by all cohort patients (n=513).

Age Group	Total Count	20/40 or better		20/41 - 20/80		20/81 - 20/100		20/101- 20/200		20/201+	
		Count	%	Count	%	Count	%	Count	%	Count	%
< = 59	29	29	100.0%	0	0.0%	0	0.0%	0	0.0%	2	6.9%
60 - 69	141	136	96.5%	5	3.6%	0	0.0%	0	0.0%	5	3.6%
70 - 79	223	213	95.5%	7	3.1%	0	0.0%	2	0.9%	1	0.5%
> = 80	120	105	87.5%	13	10.8%	1	0.8%	1	0.8%	2	1.7%
	513	**483**	**94.2%**	**25**	**4.8%**	**1**	**0.2%**	**3**	**0.6%**	**1**	**0.2%**

Table 3

ADVERSE REACTIONS

Adverse reactions were reported at the following rate for Model WS-100 silicone lens implant patients.

ADVERSE REACTIONS (CORE = 622)		
ADVERSE REACTIONS	NUMBER OF PATIENTS	PERCENTAGE
Hypopyon	4	0.7%
Intraocular Infection	2	0.3%
Acute Corneal Decompensation	0	0.0%
Surgical Reintervention	0	0.0%

TABLE 4

COMPLICATIONS

The following eleven (11) sight-threatening complications occurred following cataract extraction and intraocular lens implantation of Model WS-100 in the cohort patient population (n=513).

Postoperative Complications	Number of Patients Reported as Cumulative Count	Number of Patients Reported as Persistent Count
Corneal Edema	160	3
Iritis	274	2
Hyphema	5	0
Secondary Glaucoma	10	2
Macular Edema	6	0
Pupillary Block	1	0
Cyclitic Membrane	2	0
Vitritis	4	0
Endophthalmitis	2	0
Retinal Detachment	0	0
Lens Dislocation	0	0

BIBLIOGRAPHY

Blaydes, JE. Small incision intraocular lens: past, present and future. Developments in Ophthalmology, 1989, 18:107-110.

Brint, SF., Ostrick, DM., and Bryan, JE. Keratometric cylinder and visual performance following phacoemulsification and implantation with silicone small-incision or polymethylmethacrylate intraocular lenses. Journal of Cataract and Refractive Surgery, January 1991, 17(1):32-36.

Consultation section. Implanting silicone foldable lenses. Journal of Cataract and Refractive Surgery, March 1992, 18(2):206-214.

Cornic, JC., and Pouliquen, Y. First results with soft lens implants. Developments in Ophthalmology, 1989, 18:114-120.

Cumming, JS. Postoperative complications and uncorrected acuities after implantation of plate haptic silicone and three-piece silicone intraocular lenses. Journal of Cataract and Refractive Surgery, March 1993, 19(2):263-274.

Davison, JA. Inflammatory sequelae with silicone and three-piece silicone intraocular lenses. Journal of Cataract and Refractive Surgery, July 1992, 18(4):421-422.

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